



Patient and Family Guide to Therapy with



FazaClo[®]
(clozapine, USP)

Orally Disintegrating Tablets

Information that may help speed your recovery



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Your healthcare professional has just started you or someone you love on a new road to recovery by prescribing FazaClo (clozapine, USP) Orally Disintegrating Tablets. FazaClo can be highly effective in relieving distressing symptoms such as agitation, unusual thoughts, hearing voices, suicidal behavior, lack of motivation, and lack of interest in social activities.

FazaClo is very convenient to take. It is designed to dissolve in your mouth *with or without* water. And it tastes like a mint.

This brochure will help you to learn about FazaClo. If you have more questions about FazaClo, you should ask your healthcare professional.

Please see page 8 for important safety information.

What are FazaClo (clozapine, USP) Orally Disintegrating Tablets?

A medication that may help

FazaClo is a medication prescribed to treat the symptoms of schizophrenia and schizoaffective disorders in patients who have not had good results with other medications. FazaClo also reduces the risk of recurrent suicidal behavior in patients with these disorders.

Researchers say that clozapine, the active ingredient in FazaClo, is the most effective medication for reducing or eliminating symptoms in patients who have not had success with other products.

A medication that is convenient

FazaClo is a very special form of clozapine because it is the only one that can be taken with or without a beverage. It is also unique because it tastes like a mint. Some patients say that the minty taste of FazaClo helps them remember that they took their medication. Some also say that because FazaClo can be taken like a mint, it does not call attention to the fact that they are taking a medication.

What is schizophrenia?

One or two out of every hundred people have a mental illness called schizophrenia. The disease is often first detected when people are teenagers or young adults.

Schizophrenia is often associated with the following symptoms:

- Hearing voices
- Thinking that you are under someone's control
- Having unusual thoughts
- Lacking motivation
- Avoiding contact with others

Experiences of this sort can be very disturbing and researchers believe they may partly be caused by an imbalance of brain chemistry. However, the full cause of the illness remains unknown.



What is schizoaffective disorder?

In addition to the symptoms of schizophrenia, some patients may experience periods of either depression or excitement. Patients may have crying spells, feelings of hopelessness, fatigue or insomnia, and also may suffer from periods of lack of concentration, unrealistically grand thoughts, or emotional highs.

What is repeated suicidal tendency?

Repeated suicidal behavior sometimes accompanies schizophrenia and schizoaffective disorders. Sometimes patients hear voices commanding them to harm themselves.

Although these symptoms may be frightening and confusing, scientific research has proven that clozapine, the active ingredient in FazaClo, can often provide relief.

How FazaClo (clozapine, USP) Orally Disintegrating Tablets may help

- Over a period of time, symptoms like voices or unusual thoughts usually diminish or disappear.
- You may experience renewed interest in attending school, or holding a job; and you may want to join in more social activities with your family and friends.
- FazaClo generally produces little or none of the restlessness, stiffness, shakiness, or tremor you may have experienced with other medications.
- Since FazaClo is the only orally disintegrating tablet form of clozapine, you'll always receive refills that look and work exactly the same way.



Side effects

All medications have the risk of side effects, including FazaClo Orally Disintegrating Tablets. Among the serious side effects printed below in bold type, a rare but significant side effect associated with FazaClo is a blood disorder called agranulocytosis that causes a drop in white blood cell levels. This disorder reduces the body's ability to fight off infection. For early detection of this rare side effect, your healthcare professional will sign you up for regular blood tests. And, as a further safeguard, you will only be able to get your FazaClo prescription refill when you return regularly for testing, and the test results are favorable.

It is important to tell your healthcare professional if you experience weakness, flu-like symptoms, fever, sore throat, mouth sores, a general sense of slowness, or other possible signs of infection.

Please see the enclosed Full Prescribing Information, including BOXED WARNINGS regarding agranulocytosis, seizures, dementia-related psychosis in elderly patients, myocarditis and other adverse cardiovascular and respiratory effects. Phenylketonurics: FazaClo Orally Disintegrating Tablets contain phenylalanine.

Required lab tests

When you are first given your prescription for FazaClo (clozapine, USP) Orally Disintegrating Tablets, your healthcare professional will enroll you in the FazaClo Patient Registry. This registry helps your doctor keep track of your blood test results so that you can continue to take your FazaClo safely.

If you are new to clozapine, during the first 6 months that you are on FazaClo therapy your blood will be tested for its white blood cell count every week. The next 6 months you'll be tested just every other week, and, after a year of good blood test results, you'll only need to be tested every 4 weeks.

MONTHS 1 TO 6						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

MONTHS 7 TO 12						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

MONTHS 13+						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Tips for getting the best results

There are a number of things that you can do to help you get the best results from taking FazaClo.

- Most important, take your medication on time, as directed by your healthcare professionals. Always follow their instructions exactly, and never take more or less FazaClo tablets than your prescription calls for.
- Be patient with your medication program. It often takes 6 to 8 weeks to get to a dosage that's best for you.
- Stay on schedule. See your healthcare professionals regularly for lab tests and to report any side effects that may occur.
- If you miss any doses, call your health care professionals; and, if you've skipped doses for more than 2 days, ***don't restart your medication without first consulting with your healthcare professionals.***



How to take FazaClo (clozapine, USP) Orally Disintegrating Tablets

FazaClo tablets must remain in their package until the time of use. Peel the foil from the package and gently remove the tablet. Place the FazaClo tablet(s) in your mouth and allow it to disintegrate with your saliva. Then swallow. A beverage is not necessary to take FazaClo. If you have to split any FazaClo tablets, be sure the other half of the tablet that was not taken is disposed of safely.

Patient Health Information

The FazaClo Patient Registry is a program mandated by the Food and Drug Administration. Disclosures by healthcare professionals of patient health information for the Registry are permitted by Federal law and do not require a patient's authorization.



Useful phone numbers and web sites

FazaClo Call Center

1-877-FAZACLO (1-877-329-2256)

www.fazaclo.com

NAMI (National Alliance for the Mentally Ill)

1-800-950-NAMI (1-800-950-6264)

www.nami.org

MHA (Mental Health America)

1-800-969-6642

www.nmha.org

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